UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/741,843	12/22/2000	Shui-on Leung	018733-0996	9659

26633 7590 01/12/2006

HELLER EHRMAN WHITE & MCAULIFFE LLP
1717 RHODE ISLAND AVE, NW
WASHINGTON, DC 20036-3001

EXAMINER	
SCHWADRON, RONALD B	
ART UNIT	**PAPER NUMBER**
1644	

DATE MAILED: 01/12/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/741,843	LEUNG ET AL.	
	Examiner	Art Unit	
	Ron Schwadron, Ph.D.	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *95-149* is/are pending in the application.

4a) Of the above claim(s) *105-112,114-117,122,123,132,133,142 and 143* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *95-104,113,118-121,124-131,134-141 and 144-149* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

1. Applicant's election with traverse of Group I in the reply filed on 4/15/2002 is acknowledged. The traversal is on the ground(s) that are stated. This is not found persuasive because of the following reasons. The Office Action mailed 2/14/2002 explains why inventions I and II are distinct. Regarding applicants comments about serious burden, the M.P.E.P. § 803 states that: "For purposes of the initial requirement, a serious burden on the examiner may be *prima facie* shown if the examiner shows by appropriate explanation either separate classification, separate status in the art, or a different field of search...". The restriction requirement enunciated in the Office Action mailed 2/14/2002 meets this criterion and therefore establishes that serious burden is placed on the Examiner by the searching of additional Groups.

The requirement is still deemed proper and is therefore made FINAL.
Claims to the nonelected inventions have been cancelled.

2. Applicant's election with traverse of Group I in the reply filed on 4/10/2003 is acknowledged. The traversal is on the ground(s) that are stated. This is not found persuasive because of the following reasons. The Office Action mailed 3/10/2003, explains why inventions I and II are distinct. Regarding applicants comments about serious burden, the M.P.E.P. § 803 states that: "For purposes of the initial requirement, a serious burden on the examiner may be *prima facie* shown if the examiner shows by appropriate explanation either separate classification, separate status in the art, or a different field of search...". The restriction requirement enunciated in the Office Action mailed 3/10/2003 meets this criterion and therefore establishes that serious burden is placed on the Examiner by the searching of additional Groups.

The requirement is still deemed proper and is therefore made FINAL.
Claims to the nonelected inventions have been cancelled.

3. Applicant's election of the species antibody of SEQ ID. No 2 and 4 in the reply filed on 1/20/2004 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). Antibodies with substituted FR regions do not read on the elected species because they contain amino acids other than those found in the elected

species. The claims reading on CDRs derived from the elected species have been included as part of the elected species.

4. Claims 105-112,114-117,122,123,132,133,142,143 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 1/20/2004.

5. The abstract of the disclosure is objected to because it is more than 150 words. Correction is required. See MPEP § 608.01(b).

6. It is noted that this application appears to claim subject matter disclosed in prior Applications listed in EDAN paper TRNA 12/22/2000. A reference to the prior application must be inserted as the first sentence(s) of the specification of this application or in an application data sheet (37 CFR 1.76), if applicant intends to rely on the filing date of the prior application under 35 U.S.C. 119(e), 120, 121, or 365(c). See 37 CFR 1.78(a). For benefit claims under 35 U.S.C. 120, 121, or 365(c), the reference must include the relationship (i.e., continuation, divisional, or continuation-in-part) of all nonprovisional applications. If the application is a utility or plant application filed under 35 U.S.C. 111(a) on or after November 29, 2000, the specific reference to the prior application must be submitted during the pendency of the application and within the later of four months from the actual filing date of the application or sixteen months from the filing date of the prior application. If the application is a utility or plant application which entered the national stage from an international application filed on or after November 29, 2000, after compliance with 35 U.S.C. 371, the specific reference must be submitted during the pendency of the application and within the later of four months from the date on which the national stage commenced under 35 U.S.C. 371(b) or (f) or sixteen months from the filing date of the prior application. See 37 CFR 1.78(a)(2)(ii) and (a)(5)(ii). This time period is not extendable and a failure to submit the reference required by 35 U.S.C. 119(e) and/or 120, where applicable, within this time period is considered a waiver of any benefit of such prior application(s) under 35 U.S.C. 119(e), 120, 121 and 365(c). A benefit claim filed after the required time period may be accepted if it is accompanied by a grantable petition to accept an unintentionally delayed benefit claim under 35 U.S.C. 119(e), 120, 121 and 365(c). The petition must be accompanied by (1) the reference required by 35 U.S.C. 120 or 119(e) and 37 CFR 1.78(a)(2) or (a)(5) to the prior application (unless previously submitted), (2) a surcharge under 37 CFR 1.17(t), and (3) a statement that the entire delay between the date the claim was due under 37 CFR 1.78(a)(2) or (a)(5) and the date the claim was filed was unintentional.

The Director may require additional information where there is a question whether the delay was unintentional. The petition should be addressed to: Mail Stop Petition, Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

If the reference to the prior application was previously submitted within the time period set forth in 37 CFR 1.78(a), but not in the first sentence(s) of the specification or an application data sheet (ADS) as required by 37 CFR 1.78(a) (e.g., if the reference was submitted in an oath or declaration or the application transmittal letter), and the information concerning the benefit claim was recognized by the Office as shown by its inclusion on the first filing receipt, the petition under 37 CFR 1.78(a) and the surcharge under 37 CFR 1.17(t) are not required. Applicant is still required to submit the reference in compliance with 37 CFR 1.78(a) by filing an amendment to the first sentence(s) of the specification or an ADS. See MPEP § 201.11.

7. The remarks filed 4/8/2004 and accompanying evidence support the proposed changes to the sequences that are addressed in the remarks filed 4/8/2004

8. Claims 95-104,113,118-121,124-131,134-141,144-149 are under consideration.

9. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., In re Berg, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); In re Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); In re Longi, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); In re Van Ornum, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); In re Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and In re Thorington, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

10. Claims 95-104,113,118-121,124-131,134-141,144-149 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 25-27 of U.S. Patent No. 6,187,287. Although the conflicting claims are not identical, they are not patentably distinct from each other because while the two sets of claims differ in scope, both sets of claims encompass nucleic acids/expression vectors encoding antibodies or fragments containing SEQ. ID. No 2 and 4 or nucleic acids comprising the CDRs contained in said sequences wherein said antibodies bind the antigen bound by LL2 antibody (CD22). Myeloma cells were known in the art as host cells for vectors encoding antibodies. The nucleic acid sequences can also contain human constant region sequences (see claim 25).

11. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

12. Claims 95-104,113,120,121,124-131,136-141,146-149 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

There is no support in the specification as originally filed for the nucleic acids of claims 95-100. Regarding applicants comments, original claims 6-11 are not drawn to nucleic acids, they are drawn to peptides. There is no disclosure in the specification as originally filed of the claimed nucleic acids. In addition, the claimed nucleic acids encompass nucleic acids comprising the recited CDR and nucleic acids that do not encode amino acids and there is no disclosure in the specification as originally filed of such nucleic acids.

There is no support in the specification as originally filed for the nucleic acids (or vectors or cells containing said nucleic acids) of claims 101-104,120,121,124-130,136-140,146-149. The claims encompass nucleic acids encoding variable heavy chain and or variable light chains wherein said nucleic acids encode less than all of the CDRs found in the LL2 heavy and or light chain variable chain regions. There is no disclosure in the specification as originally

filed of such nucleic acids. The disclosure in the specification is limited to nucleic acids that encode variable heavy and/or variable light chains from the chimeric LL2 antibody or humanized LL2 antibody wherein said nucleic acids encode all of the CDRs derived the murine LL2 antibody. The passages of the specification to which applicant refers disclose nucleic acids that encode variable heavy and/or variable light chains from the chimeric LL2 antibody or humanized LL2 antibody wherein said nucleic acids encode all of the CDRs derived the murine LL2 antibody.

There is no support in the specification as originally filed for the nucleic acids (or vectors or cells containing said nucleic acids) of claims 113,131,141. The specification discloses chimeric LL2 antibody or humanized LL2 antibody wherein said nucleic acids encode all of the CDRs derived the murine LL2 antibody and contain human FR regions (humanized) or the FR regions of the murine LL2 antibody. The claims encompass nucleic acids encoding heavy and or light chain variable regions that contain FR regions not derived from LL2 or not derived from human FR regions and there is no disclosure of such nucleic acids in the specification as originally filed.

There is no support in the specification as originally filed for the cells of claims 127,128,129,137,138,139,147,148,149. The specification discloses the use of "mammalian expression cells", but does not disclose the scope of claims which do not include said limitation. Regarding claims 129/139/149, the specification discloses use of "SP2 cells", but does not disclose the scope of the claimed method which encompasses use of myeloma cells derived from any source.

There is no support in the specification as originally filed for the invention of claim 120, wherein said claim encompasses binding of CD22 epitopes other than the epitope bound by the LL2 antibody.

There is no support in the specification as originally filed for the expression vectors of claims 126,136,146. the specification discloses use of "mammalian expression vectors", but not the use of vectors per se wherein said term would encompass nonmammalian expression vectors.

There is no written description of the claimed inventions in the specification as originally filed (the claimed inventions constitute new matter).

13. Regarding claims 95-104,113,120,121,124-131,136-141,146-149 and the application of prior art, for the same reasons that said claims constitute new matter, they are not entitled to priority to the parent applications to which priority is claimed.

14. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

15. Claims 95-104,113,120,121,124-131,136-141,146-149 are rejected under 35 U.S.C. 102(b) as being anticipated by Leung et al. (US Patent 5,789,554).

Leung et al. teach nucleic acids encoding the chimeric LL2 antibody which contains the nucleic acids encoding the variable heavy and light chains of the murine LL2 wherein said chains have the CDRs recited in the claims (see Example 4 and Figures 4a and 4b). Leung et al. teach vectors and a myeloma host cell containing said nucleic acids (see Example 4). All of the instant polynucleotide claims are considered "open" and therefore encompass the nucleic acids encoding the chimeric LL2 antibody. Leung et al. disclose that the nucleic acids can also include human constant regions (see Example 4).

16. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

17. Claims 95-104,113,118-121,124-131,134-141,144-149 are rejected under 35 U.S.C. § 103 as being unpatentable over Goldenberg et al. (J. Clin. Oncol.) in view of Morrison et al., Cabilly et al., Boss et al., Orlandi et al., and Huston et al. (US Patent 5,258,498).

Goldenberg et al. teach the murine LL2 monoclonal antibody and hybridoma producing said antibody (see page 549). Goldenberg et al. teach that administration of said antibody provokes a HAMA response in some patients (see abstract). The claimed nucleic acids encode peptides which encompass or contain the CDR(s) found in the VH and VL of said antibody. The hybridoma which produces murine LL2 antibody produces the claimed nucleic acids which encode the VH and VL of said antibody. Goldenberg et al. do not teach the claimed isolated nucleic acids and vectors or host cells containing said nucleic acids. Morrison et al. teach chimeric antibodies containing variable regions from a known mouse antibody attached to human constant regions (see abstract and columns 1-8). Morrison et al. disclose nucleic acids encoding variable light and heavy chains of a murine antibody attached to nucleic acids encoding human constant regions (see column 3-6). Morrison et al. disclose that the nucleic acids encoding the murine variable regions would be obtained by routine experimentation (see column 3). The nucleic acids are expressed in vectors (see column 6, penultimate paragraph) which can be transfected into myeloma cells (see column 7, second paragraph). Orlandi et al. also teaches primers and the use of said primers to clone DNA encoding murine variable heavy and light regions (eg. see abstract and page 3833, second column and page 3834). Both Cabilly et al. and Boss et al. disclose methods for the determination of nucleic acids encoding VH and VL of any known antibody. Huston et al. teaches that regarding the determination of the sequence of VH and VL from any desired antibody that "Such sequence analysis is now conducted routinely." (see column 13).

Thus, the art taught the murine LL2 antibody, nucleic acids encoding VH and VL and methods of producing VH and VL amino acid sequences encoding any known antibody wherein said methods used a hybridoma which produced said antibody. Said nucleic acids would have been used to produce chimeric antibodies as per taught by Morrison et al. It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have created the claimed invention because Goldenberg et al. teach the murine LL2 monoclonal antibody wherein said antibody is produced by a hybridoma, and the references cited in this rejection teach chimeric antibodies, nucleic acids encoding VH and VL, and methods of making chimeric antibodies based on the nucleic acid sequence of any known antibody VH and VL, and methods of determining the nucleic acid sequence of any known antibody VH and VL.

All variable regions are structurally similar in that they contain similar numbers of amino acids organized in a similar fashion (eg. they contain a VH and VL wherein the VH and VL contain framework and variable region amino acids). Regarding motivation to create the claimed invention, Goldenberg et al. disclose clinical use of the murine LL2 antibody and the art recognized the advantages of antibodies encoded by nucleic acids encoding chimeric antibodies (see Morrison et al., column 7, last paragraph, continued on column 8, Orlandi et al., page 3833, first column, first paragraph).

18. No claim is allowed.

19. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ron Schwadron, Ph.D. whose telephone number is 571 272-0851. The examiner can normally be reached on Monday-Thursday 7:30-6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571 272-0841. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Ron Schwadron, Ph.D.
Primary Examiner
Art Unit 1644

RONALD SCHWADRON
PRIMARY EXAMINER
GROUP ~~1600~~ 1600